OIPE
AUG 29 2005
PATENT & TRADEMARK OFFICE

AF 1631 ⅀FW

PTO/SB/21 (09-04)

# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

| | |
|---|---|
| Application Number | 09/271,411 |
| Filing Date | March 17, 1999 |
| First Named Inventor | Northrup, M. Allen |
| Art Unit | 1631 |
| Examiner Name | Marschel, Ardin H. |
| Attorney Docket Number | 020048-002810US |
| Total Number of Pages in This Submission | 19 |

## ENCLOSURES *(Check all that apply)*

- [ ] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) ____________
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please identify below):

Return Postcard
Amended Appellant's Brief

Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | |
|---|---|
| Firm Name | Townsend and Townsend and Crew LLP |
| Signature | [signature] |
| Printed name | Chun-Pok Leung |
| Date | August 26, 2005 |
| Reg. No. | 41,405 |

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: **Mail Stop Appeal Brief - Patents,** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

| | |
|---|---|
| Signature | [signature] |
| Typed or printed name | Joy Salvador |
| Date | August 26, 2005 |

60573642 v1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

| | |
|---|---|
| In re application of: | Examiner: MARSCHEL, ARDIN H. |
| M. ALLEN NORTHRUP et al. | Art Unit: 1631 |
| Application No.: 09/271,411 | Confirmation No.: 4121 |
| Filed: March 17, 1999 | **AMENDED** APPELLANT'S BRIEF UNDER 37 CFR § 1.192 |
| For: SAMPLE ANALYSIS DEVICE HAVING A REACTION CHAMBER, TRANSITION REGION, AND SEPARATION REGION AND METHOD OF USE | |

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants, in the above-captioned patent application, appeal the final rejection of claims 45-50, 52-55, 57, 58, 60 and 62-70. The claims on appeal have been finally rejected pursuant to MPEP § 706.07(b). Accordingly, this appeal is believed to be proper.

I. REAL PARTY IN INTEREST:

The real party in interest for the above-identified application is CEPHEID, a California corporation having its principal place of business at 904 Caribbean Drive, Sunnyvale, California 94089. The assignment was recorded in the U.S. Patent and Trademark Office on March 17, 1999 at Reel 9838/Frame 0977.

II. RELATED APPEALS AND INTERFERENCES:

There are no appeals or interferences related to the present appeal.

III. STATUS OF CLAIMS:

Claims 45-55 and 57-71 are pending.

Claims 45-50, 52-55, 57, 58, 60 and 62-70 were rejected under 35 U.S.C. § 103(a) upon the grounds set forth in the Final Office Action mailed on June 9, 2004.

Claims 51, 59, 61, and 71 were objected to as being dependent upon rejected base claims.

IV. STATUS OF AMENDMENTS:

Applicants filed a Response under 37 C.F.R. § 1.116 on November 9, 2004. No amendments were made. An Advisory Action mailed January 21, 2005 indicated that the Response did not place the application in condition for allowance.

In accordance with 37 C.F.R. § 1.192(c)(9), a copy of the claims involved in the appeal are contained in the Appendix attached hereto.

V. SUMMARY OF CLAIMED SUBJECT MATTER:

This application discloses a device (claims 45-55 and 57-59) and method (claims 60-71) for analyzing a sample.

In the embodiment of independent claim 45, as illustrated in Figs. 1-6, a device (2 or 150) for analyzing a sample comprises a body (4) having a reaction chamber (6 or 40 or 154) for conducting a reaction, a separation channel (8, 32, 50, or 158) for separating sample components, and a transition region (60 or 156) connecting the reaction chamber to the separation channel. The portion of the body defining the transition region has sufficiently low thermal conduction so that the transition region substantially thermally isolates the reaction chamber from the separation channel. The device also comprises at least one valve (64, 68, 69, 180, or 182) in the transition region for controlling fluid flow between the reaction chamber and the separation channel. The device further comprises at least two electrodes (20, 22, or 51, 53, 55, or 70a, 70B, or 167, 168, 169) coupled to the body, the electrodes being positioned to induce electrophoretic flow, electroosmotic flow, or isoelectric focusing of the sample components in the separation channel when a voltage difference is applied between the electrodes.

In the embodiment of independent method claim 60, as illustrated in Figs. 1-6, a method for analyzing a sample comprises the steps of introducing the sample into a device (2 or 150) having a reaction chamber (6 or 40 or 154), a separation region (8, 32, 50, or 158), a

transition region (60 or 156) connecting the reaction chamber to the separation region, at least one valve (64, 68, 69, 180, or 182) in the transition region. The transition region has sufficiently low thermal conduction so that the transition region substantially thermally isolates the reaction chamber from the separation region. The sample is subjected to a reaction in the reaction chamber while the valve is closed. The transition region substantially thermally isolates the reaction chamber from the separation region during the reaction. The method also comprises the steps of opening the valve, injecting into the separation region a sample plug containing reaction products, separating the reaction products in the separation region, and detecting the separated reaction products.

VI. <u>GROUNDS OF REJECTION PRESENTED FOR REVIEW:</u>

A. Claims 45-50, 52-55, 57, 58, 60, and 62-70 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Handique (P/N 6,130,098).

B. Claims 45-50, 52-55, 57, 58, 60, and 62-70 stand rejected under 35 U.S.C. § 103(a) as being obvious over Handique (6,130,098) in view of Wilding (P/N 5,587,128), or alternatively, over Wilding in view of Handique.

VII. <u>ARGUMENTS:</u>

A. <u>Rejection of Claims 45-50, 52-55, 57, 58, 60, and 62-70 over Handique</u>

1. <u>Claim 45 and dependent claims 46-50, 52-55, 57, and 58 are not properly rejected under 35 U.S.C. § 103(a) as unpatentable over Handique (P/N 6,130,098)</u>

Applicants respectfully submit that independent claim 45 is patentable over Handique because, for instance, Handique fails to teach or suggest the feature of Applicants' claim 45:

> at least one valve in the transition region for controlling fluid flow between the reaction chamber and the separation channel.

In Fig. 1, Handique shows a device having a reaction chamber connected to an electrophoresis module, but no valve is shown in the region connecting the reaction chamber to

 

the electrophoresis module. In fact, there are no valves shown in Fig. 1. Where Handique shows a valve is in the different device of Fig. 13. In Fig. 13, Handique shows a different device having a valve in a side channel connecting to a main channel. However, this different device shown in Fig. 13 lacks a reaction chamber or electrophoresis module. Thus, this showing of a valve in a side channel in the device of Fig. 13 does not fairly teach or suggest Applicants' device as recited in claim 45. There is no showing in Fig. 13, or anywhere else in Handique, of a valve in a transition region for controlling fluid flow between a reaction chamber and a separation channel, as recited by Applicants in claim 45. The placement of a valve in a side channel of the device of Fig. 13 does not teach or suggest the placing of a valve in the region of the different device of Fig. 1 that connects the reaction chamber to the electrophoresis module.

The devices of the cited art fail to provide for control of fluid between reaction and separation regions. High internal pressure can develop in a reaction chamber due to the thermal expansion of liquid or gas present in this region, the generation of gas bubbles, or the chemical reactions performed inside of the chamber. This pressure, combined with any elevated temperatures within the chamber, can have detrimental effects on the separation medium (e.g., gel) in the separation channel. A particular problem is the flow or diffusion of chemicals from the reaction chamber into the separation region caused by the elevated pressure or temperature in the reaction chamber. This situation is especially problematic when sensitive detection methods and apparatus are located downstream from the reaction chamber. Applicants' device as recited in claim 45 overcome these problems with at least one valve in a transition region between the reaction chamber and separation region, which provides for fluid flow control and thermal isolation of the reaction chamber from the separation channel.

Moreover, Handique teaches away from placing valves in the device of Fig. 1. In the section of the specification (Col. 13, lines 61-66) following the description of Fig. 1, when describing how discreet droplets are created and moved through the device, Handique teaches that "The present invention contemplates methods, compositions and devices for the creation of microdroplets of discrete (i.e., controlled and predetermined) size. The present invention contemplates the use of selective hydrophobic coatings to develop a liquid-sample injection and motion system that <u>does not require the use of valves</u>." Thus, Handique fails to

teach or suggest that there should be any valves in the device of Fig. 1, much less that there should be a valve in the transition region for controlling fluid flow between the reaction chamber and the separation channel, as explicitly recited by Applicants in claim 45.

For at least the foregoing reasons, independent claim 45 and claims 46-55 and 57-59 depending therefrom are patentable.

2. Claim 60 and dependent claims 62-70 are not properly rejected under 35 U.S.C. § 103(a) as unpatentable over Handique (P/N 6,130,098)

Applicants respectfully submit that independent claim 60 is patentable over Handique because, for instance, Handique fails to show at least one valve in the transition region for controlling fluid flow between the reaction chamber and the separation channel and, lacking a valve, Handique also necessarily fails to teach or suggest the method steps recited in claim 60 of subjecting the sample to a reaction while the valve is closed and then opening the valve before injecting a sample plug into the separation region.

In Fig. 1, Handique shows a device having a reaction chamber connected to an electrophoresis module, but no valve is shown in the region connecting the reaction chamber to the electrophoresis module. In fact, there are no valves shown in Fig. 1. Where Handique shows a valve is in the different device of Fig. 13. In Fig. 13, Handique shows a different device having a valve in a side channel connecting to a main channel. However, this different device shown in Fig. 13 lacks a reaction chamber or electrophoresis module. Thus, this showing of a valve in a side channel in the device of Fig. 13 does not fairly teach or suggest Applicants' method as recited in claim 60. There is no showing in Fig. 13, or anywhere else in Handique, of a valve in a transition region for controlling fluid flow between a reaction chamber and a separation channel, as recited by Applicants in claim 60. The placement of a valve in a side channel of the device of Fig. 13 does not teach or suggest the placing of a valve in the region of the different device of Fig. 1 that connects the reaction chamber to the electrophoresis module.

The devices of the cited art fail to provide for control of fluid between reaction and separation regions. High internal pressure can develop in a reaction chamber due to the thermal expansion of liquid or gas present in this region, the generation of gas bubbles, or the

chemical reactions performed inside of the chamber. This pressure, combined with any elevated temperatures within the chamber, can have detrimental effects on the separation medium (e.g., gel) in the separation channel. A particular problem is the flow or diffusion of chemicals from the reaction chamber into the separation region caused by the elevated pressure or temperature in the reaction chamber. This situation is especially problematic when sensitive detection methods and apparatus are located downstream from the reaction chamber. Applicants' method as recited in claim 60 overcome these problems with at least one valve in a transition region between the reaction chamber and separation region, which provides for fluid flow control and thermal isolation of the reaction chamber from the separation channel.

Moreover, Handique teaches away from using valves in the device of Fig. 1. In the section of the specification (Col. 13, lines 61-66) following the description of Fig. 1, when describing how discreet droplets are created and moved through the device, Handique teaches that "The present invention contemplates methods, compositions and devices for the creation of microdroplets of discrete (i.e., controlled and predetermined) size. The present invention contemplates the use of selective hydrophobic coatings to develop a liquid-sample injection and motion system that <u>does not require the use of valves</u>." Thus, Handique fails to teach or suggest that there should be any valves used in the device of Fig. 1, much less that there should be a valve in the transition region that is closed while a sample is reacted in the reaction chamber and opened before injecting a sample plug into the separation region, as explicitly recited by Applicants in claim 60.

For at least the foregoing reasons, independent claim 60 and claims 61-71 depending therefrom are patentable.

B. Rejection of Claims 45-50, 52-55, 57, 58, 60, and 62-70 over Handique and Wilding

1. Claim 45 and dependent claims 46-50, 52-55, 57, and 58 are not properly rejected under 35 U.S.C. § 103(a) as being obvious over Handique (6,130,098) in view of Wilding (P/N 5,587,128), or alternatively, over Wilding in view of Handique

Applicants respectfully submit that independent claim 45 is patentable over Handique alone or in combination with Wilding because no combination of these references teaches a device having:

> at least one valve in the transition region for controlling fluid flow between the reaction chamber and the separation channel.

In Fig. 1, Handique shows a device having a reaction chamber connected to an electrophoresis module, but no valve is shown in the region connecting the reaction chamber to the electrophoresis module. In fact, there are no valves shown in Fig. 1. Where Handique shows a valve is in the different device of Fig. 13. In Fig. 13, Handique shows a different device having a valve in a side channel connecting to a main channel. However, this different device shown in Fig. 13 lacks a reaction chamber or electrophoresis module. Thus, this showing of a valve in a side channel in the device of Fig. 13 does not fairly teach or suggest Applicants' device as recited in claim 45. There is no showing in Fig. 13, or anywhere else in Handique, of a valve in a transition region for controlling fluid flow between a reaction chamber and a separation channel, as recited by Applicants in claim 45. The placement of a valve in a side channel of the device of Fig. 13 does not teach or suggest the placing of a valve in the region of the different device of Fig. 1 that connects the reaction chamber to the electrophoresis module.

The devices of the cited art fail to provide for control of fluid between reaction and separation regions. High internal pressure can develop in a reaction chamber due to the thermal expansion of liquid or gas present in this region, the generation of gas bubbles, or the chemical reactions performed inside of the chamber. This pressure, combined with any elevated temperatures within the chamber, can have detrimental effects on the separation medium (e.g., gel) in the separation channel. A particular problem is the flow or diffusion of chemicals from the reaction chamber into the separation region caused by the elevated pressure

or temperature in the reaction chamber. This situation is especially problematic when sensitive detection methods and apparatus are located downstream from the reaction chamber. Applicants' device as recited in claim 45 overcome these problems with at least one valve in a transition region between the reaction chamber and separation region, which provides for fluid flow control and thermal isolation of the reaction chamber from the separation channel.

Moreover, Handique teaches away from placing valves in the device of Fig. 1. In the section of the specification (Col. 13, lines 61-66) following the description of Fig. 1, when describing how discreet droplets are created and moved through the device, Handique teaches that "The present invention contemplates methods, compositions and devices for the creation of microdroplets of discrete (i.e., controlled and predetermined) size. The present invention contemplates the use of selective hydrophobic coatings to develop a liquid-sample injection and motion system that <u>does not require the use of valves</u>." Thus, Handique fails to teach or suggest that there should be any valves in the device of Fig. 1, much less that there should be a valve in the transition region for controlling fluid flow between the reaction chamber and the separation channel, as explicitly recited by Applicants in claim 45.

The Wilding reference also fails to teach or suggest a device having a valve in a transition region that connects a reaction chamber to a separation channel. Wilding therefore fails to remedy the shortcomings of Handique. Thus, neither Handique nor any combination of Handique and Wilding render obvious the Applicants' invention as recited in claim 45.

For at least the foregoing reasons, independent claim 45 and claims 46-55 and 57-59 depending therefrom are patentable.

2. <u>Claim 60 and dependent claims 62-70 are not properly rejected under 35 U.S.C. § 103(a) as being obvious over Handique (6,130,098) in view of Wilding (P/N 5,587,128), or alternatively, over Wilding in view of Handique.</u>

Applicants respectfully submit that independent claim 60 is patentable over Handique alone or in combination with Wilding because no combination of these references shows at least one valve in a transition region for controlling fluid flow between the reaction chamber and the separation channel and, lacking a valve, the references also necessarily fails to teach or suggest the method steps recited in claim 60 of subjecting the sample to a reaction

while the valve is closed and then opening the valve before injecting a sample plug into the separation region.

In Fig. 1, Handique shows a device having a reaction chamber connected to an electrophoresis module, but no valve is shown in the region connecting the reaction chamber to the electrophoresis module. In fact, there are no valves shown in Fig. 1. Where Handique shows a valve is in the different device of Fig. 13. In Fig. 13, Handique shows a different device having a valve in a side channel connecting to a main channel. However, this different device shown in Fig. 13 lacks a reaction chamber or electrophoresis module. Thus, this showing of a valve in a side channel in the device of Fig. 13 does not fairly teach or suggest Applicants' method as recited in claim 60. There is no showing in Fig. 13, or anywhere else in Handique, of a valve in a transition region for controlling fluid flow between a reaction chamber and a separation channel, as recited by Applicants in claim 60. The placement of a valve in a side channel of the device of Fig. 13 does not teach or suggest the placing of a valve in the region of the different device of Fig. 1 that connects the reaction chamber to the electrophoresis module.

The devices of the cited art fail to provide for control of fluid between reaction and separation regions. High internal pressure can develop in a reaction chamber due to the thermal expansion of liquid or gas present in this region, the generation of gas bubbles, or the chemical reactions performed inside of the chamber. This pressure, combined with any elevated temperatures within the chamber, can have detrimental effects on the separation medium (e.g., gel) in the separation channel. A particular problem is the flow or diffusion of chemicals from the reaction chamber into the separation region caused by the elevated pressure or temperature in the reaction chamber. This situation is especially problematic when sensitive detection methods and apparatus are located downstream from the reaction chamber. Applicants' method as recited in claim 60 overcome these problems with at least one valve in a transition region between the reaction chamber and separation region, which provides for fluid flow control and thermal isolation of the reaction chamber from the separation channel.

Moreover, Handique teaches away from using valves in the device of Fig. 1. In the section of the specification (Col. 13, lines 61-66) following the description of Fig. 1, when describing how discreet droplets are created and moved through the device, Handique teaches

that "The present invention contemplates methods, compositions and devices for the creation of microdroplets of discrete (i.e., controlled and predetermined) size. The present invention contemplates the use of selective hydrophobic coatings to develop a liquid-sample injection and motion system that does not require the use of valves." Thus, Handique fails to teach or suggest that there should be any valves used in the device of Fig. 1, much less that there should be a valve in the transition region that is closed while a sample is reacted in the reaction chamber and opened before injecting a sample plug into the separation region, as explicitly recited by Applicants in claim 60.

The Wilding reference also fails to teach or suggest a device having a valve in a transition region that connects a reaction chamber to a separation channel and, lacking a valve, Wilding also necessarily fails to teach or suggest the method steps recited in claim 60 of subjecting the sample to a reaction while the valve is closed and then opening the valve before injecting a sample plug into the separation region. Wilding therefore fails to remedy the shortcomings of Handique. Thus, neither Handique nor any combination of Handique and Wilding render obvious the Applicants' invention as recited in claim 60.

For at least the foregoing reasons, independent claim 60 and claims 61-71 depending therefrom are patentable.

## VIII. CONCLUSION:

In view of the foregoing arguments distinguishing claims 45-55 and 57-71 over the art of record, Applicants respectfully submit that the claims are in condition for allowance, and respectfully request that the rejection of these claims be reversed.

Respectfully submitted,

Chun-Pok Leung
Reg. No. 41,405

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200;
Fax: (415) 576-0300
RL
60421128 v1

Encl.: Appendix of claims involved in appeal
Related Proceeding Appendix (none)
Evidence Appendix (none)

Claims APPENDIX

1-44. (canceled)

45. (previously presented) A device for analyzing a sample, the device comprising:

a) a body having:

i) a reaction chamber for conducting a reaction;

ii) a separation channel for separating sample components;

iii) a transition region connecting the reaction chamber to the separation channel, wherein the portion of the body defining the transition region has sufficiently low thermal conduction so that the transition region substantially thermally isolates the reaction chamber from the separation channel; and

iv) at least one valve in the transition region for controlling fluid flow between the reaction chamber and the separation channel; and

b) at least two electrodes coupled to the body, the electrodes being positioned to induce electrophoretic flow, electroosmotic flow, or isoelectric focusing of the sample components in the separation channel when a voltage difference is applied between the electrodes.

46. (previously presented) In combination with the device of claim 45, an instrument into which the device may be inserted, the instrument having electrical connections for applying the voltage difference between the electrodes and having at least one light source and detector for detecting the sample components in the separation channel.

47. (previously presented) The combination of claim 46, wherein the instrument further includes a heater for heating the reaction chamber.

48. (previously presented) The combination of claim 46, wherein the instrument includes additional optics for monitoring the reaction chamber.

49. (previously presented) The device of claim 45, wherein the body further includes:

a) a side channel connected to the transition region for adding or removing fluid from the transition region; and

b) at least a second valve for controlling fluid flow through the side channel.

50. (previously presented) In combination with the device of claim 49, an instrument into which the device may be inserted, wherein the valves comprise membrane valves, the instrument has electrical connections for applying the voltage difference between the electrodes, and the instrument further has means for controlling the membrane valves.

51. (previously presented) The combination of claim 50, wherein the instrument pneumatically controls the membrane valves.

52. (previously presented) The device of claim 45, wherein the valve comprises a mechanical valve having an open position and a closed position.

53. (previously presented) The device of claim 45, wherein the body further includes an inlet port for adding the sample and reagents to the reaction chamber.

54. (previously presented) The device of claim 45, wherein the body comprises a one-piece polymeric body having the reaction chamber, transition region, and separation channel formed therein.

55. (previously amended) The device of claim 45, wherein the separation channel comprises an electrophoresis or isoelectric focusing channel containing separation material.

56. (canceled).

57. (previously presented) The device of claim 45, wherein each of the electrodes is embedded in the body such that one end of the electrode protrudes through an external surface of the body and such that the other end of the electrode protrudes into an internal region of the body.

58. (previously presented) The device of claim 45, wherein the body comprises a polymeric material, and wherein the electrodes are over-molded in the body.

59. (previously presented) The device of claim 45, wherein the electrodes are screen-printed on the body.

60. (previously presented) A method for analyzing a sample, the method comprising the steps of:

a) introducing the sample into a device having:
   i) a reaction chamber;
   ii) a separation region;
   iii) a transition region connecting the reaction chamber to the separation region, wherein the transition region has sufficiently low thermal conduction so that the transition region substantially thermally isolates the reaction chamber from the separation region; and
   iv) at least one valve in the transition region;
b) subjecting the sample to a reaction in the reaction chamber while the valve is closed, wherein the transition region substantially thermally isolates the reaction chamber from the separation region during the reaction;
c) opening the valve;
d) injecting into the separation region a sample plug containing reaction products;
e) separating the reaction products in the separation region; and
f) detecting the separated reaction products.

61. (previously presented) The method of claim 60, further comprising the steps of:

i) optically monitoring the reaction products contained in the reaction chamber; and
ii) determining if sufficient reaction products have been generated within the reaction chamber prior to injecting the sample plug into the separation region.

62. (previously presented) The method of claim 60, wherein the reaction comprises a nucleic acid amplification reaction, and wherein the reaction products comprise amplified nucleic acid.

63. (previously presented) The method of claim 60, wherein the plug is injected into the separation region by electrophoretic injection.

64. (previously presented) The method of claim 60, wherein:
    i) the device includes a body defining the reaction chamber, separation region, and transition region, and wherein the separation region comprises a separation channel;
    ii) the device further includes at least two electrodes coupled to the body, the electrodes being positioned to induce electrophoretic flow, electroosmotic flow, or isoelectric focusing of the reaction products in the separation channel when a voltage difference is applied between the electrodes;
    iii) the method further comprises the step of inserting the device into an instrument having electrical connections for applying the voltage difference between the electrodes and having at least one light source and detector for detecting the reaction products in the separation channel; and
    iv) the steps of separating and detecting the reaction products comprise applying the voltage difference through the electrical connections in the instrument and detecting the reaction products using the at least one light source and detector.

65. (previously presented) The method of claim 64, wherein the instrument further includes a heater for heating the reaction chamber, and wherein the step of subjecting the sample to the reaction comprises heating the reaction chamber with the heater.

66. (previously presented) The method of claim 60, wherein:
    i) the device further includes a side channel connected to the transition region; and

ii) the method further comprises the step of adding fluid to or removing fluid from the transition region through the side channel prior to, during, or after the step of injecting the sample plug into the separation region.

67. (previously presented) The method of claim 60, wherein:

i) the device further includes a side channel connected to the transition region; and

ii) the method further comprises the steps of adding reagents to the transition region through the side channel and mixing the reaction products with the reagents in the transition region prior to the step of injecting the sample plug into the separation region.

68. (previously presented) The method of claim 60, wherein:

i) the device further includes a side channel connected to the transition region; and

ii) the method further comprises the steps of adding buffer solution to the transition region through the side channel and injecting the buffer solution into the separation region prior to the step of injecting the sample plug into the separation region.

69. (previously presented) The method of claim 66, wherein the device further includes at least a second valve for controlling fluid flow through the side channel, and wherein the method further comprises the step of opening and closing the second valve to control fluid flow through the side channel.

70. (previously presented) The method of claim 60, wherein the reaction products are separated by electrophoresis.

71. (previously presented) The method of claim 60, wherein the reaction products are separated by isoelectric focusing.

Related Proceedings Appendix

none

Evidence Appendix

none